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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,132	05/29/2001	Knut E. Rasmussen	01-11 US	9635

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EXAMINER	
PADMANABHAN, KARTIC	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 03/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/857,132	RASMUSSEN ET AL.	
	Examiner	Art Unit	
	Kartic Padmanabhan	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 60 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s) or amend the claim(s) to place the claim(s) in proper dependent form. Claim 60 recites the way in which a component of an apparatus is formed; however, the method of formation is not given patentable weight in a claim drawn to a device.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 21-30 and 60-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 21 is rejected as vague and indefinite for the recitation of a membrane within fibre pores because it is unclear if there is a membrane within every fibre pore. It is also unclear as to which component is permeable by the analyte: the individual fibre pores, the membranes within these pores, or both.

5. Claim 60 recites the limitation "the liquid film" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

6. Claim 61 recites the limitation "the hydrophobic carrier" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 21-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasmussen et al. (WO 97/25606) in view of Berg (US Pat. 6,164,144) and Schoonen et al. (US Pat. 5,615,671).

Rasmussen et al. teach a device and method for liquid-liquid microextraction. The

method comprises proving a carrier, modifying the carrier, immobilizing a solvent (acceptor solution) on the carrier surface, contacting the carrier with the sample (which may be in solution), concentrating and fixing the analyte of interest to the solvent, and analyzing the carrier. Preferably, a fiber is used as the carrier. The fibers for use with the invention may be made of porous polymers such as polyacrylate. The amount of solvent to be immobilized on the carrier is in the range of 1-5 ul (page 4). The carrier with immobilized solvent is inserted into the sample solution, where the pH may be altered to favor partitioning of analyte and solvent (page 5). The solvent of the reference is preferably a high boiling solvent, such as octanol (page 5). In one embodiment, the fiber is withdrawn into the needle of a syringe, and the needle is used to penetrate the septum of a solvent vial, at which time the fiber is lowered and solvent is immobilized. The fiber is then withdrawn back into the needle and used to penetrate the sample vial. After the fiber is lowered into the vial, analytes are partitioned by agitating the vial (page 7). Since the fiber only accommodates 1-5 ul of sample, it is inherent that the sample vial has a volume greater than 50X this amount. The sample solution for use with the invention may be plasma. However, the reference does not specifically teach the use of a hollow fiber permeable to analyte or an acidified acceptor solution.

Berg teaches methods and device for solid phase microextraction (SPME). The reference teaches the use of a hollow fiber with SPME, wherein the fiber acts as a "sponge". In addition, the reference also teaches the use of a magnetic stirring bar as the means of agitation of a sample in a vial. However, neither Rasmussen nor Berg teach the permeability of the hollow fiber to analyte.

Schoonen et al. teach a process and device for monitoring analyte levels, wherein a tissue is provided with a hollow fiber having a pore size between the size of the analyte and the size of macromolecules. A second hollow fiber is also provided that is permeable for analyte but nor for the macromolecules.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use a hollow fiber permeable to analyte and an acidified acceptor solution as taught by Berg and Schoonen et al. with the invention of Rasmussen et al. By using a hollow fiber, one would have been able to fill the fiber with acceptor solution rather than immobilizing the solution on the surface of the fiber. With such an arrangement, partitioning will occur between analyte and acceptor within the porous fiber, at which time acceptor solution with analyte can be removed and analyzed. Alternatively, if desired, one could have also allowed analyte to permeate through the other side of the fiber before collection for analysis. One would have been able to use this arrangement with a reasonable expectation that it would provide results similar to those when acceptor is immobilized on the surface of the fiber. Depending on the analyte of interest, one of ordinary skill in the art would have had a reasonable expectation of success in selecting hollow fibers with pores of the required size such that analyte would be permeable to the desired analyte. It would have also been obvious to acidify the acceptor solution of Rasmussen et al. because Diazepam, the analyte of interest in Example 1, has its highest partition coefficient at an acidic pH. In addition, although Berg deals with solid phase microextraction, the teaching of Berg would have been applicable to the modified method of Rasmussen et al. because Rasmussen et al. use a SPME fiber in their liquid-liquid microextraction method (page 10).

11. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rasmussen et al. (WO 97/25606) in view of Berg (US Pat. 6,164,144) and Schoonen et al. (US Pat. 5,615,671) as applied to claims 21-60 above, and further in view of Atwater et al. (US Pat. 5,910,448).

Rasmussen et al., Berg, and Schoonen et al. teach a modified extraction method and device, as previously discussed. However, the references do not teach a polypropylene hollow fiber.

Atwater et al. teach a process for carbon dioxide analysis, wherein a membrane is used that preferably comprises polypropylene hollow fibers that allows for both gas-liquid and liquid-liquid analyte exchange.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the polypropylene hollow fiber of Atwater et al. with the modified device and method of Rasmussen et al., Berg, and Schoonen et al. because Rasmussen et al. teach that a variety of materials may be used as the carrier, including fibers made of porous polymers, thereby providing one with a reasonable expectation of success in using polypropylene.

Response to Arguments

12. Applicant's arguments filed 11/29/04 have been fully considered but they are not persuasive.

13. Applicant argues that the unsupported opinions of the Examiner cannot be used as the factual basis for a determination of obviousness. While this indeed may be true, the examiner maintains that the references themselves provide the factual basis, and the examiner has merely provided a statement of motivation in combining the references to arrive at the claimed invention. As long as there is motivation to combine available in the knowledge generally

available to one of ordinary skill in the art, as the examiner maintains is the case here (See text of 35 USC 103 rejections above), the combination of references is appropriate. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). Further, while applicant may be correct in asserting that subjective opinions are of little weight against contrary evidence, applicant has failed to provide any such evidence and has merely provided their own subjective opinions in response to the examiner's showing of obviousness.

14. Applicant argues that the Schoonen reference fails to teach a second hollow container disposed within a first container. While this may indeed be true, as a tertiary reference, it was only relied upon for the teaching of the permeability of the hollow fiber to analyte, as Rasmussen, as the primary reference, already taught multiple containers in the relationship required of the claims.

15. Applicant also argues that Rasmussen and Berg only teach separation of analyte using surface phenomenon; while this is true, Schoonen was relied upon to cure this deficiency. Applicant's arguments that the combination of these references with Schoonen would destroy the invention of the references is not convincing. Although Rasmussen and Berg are based on surface phenomenon, the combination with Schoonen provides an advantage over surface phenomenon for reasons discussed above. In addition, simply because Rasmussen and Berg teach surface phenomenon, this, in no way, signifies a teaching away from a combination with Schoonen. As far as the examiner is aware, neither reference explicitly states that permeability to analyte would defeat the purpose of the invention, such that only surface phenomenon is practicable. Further, applicant's characterization of the examiner's conclusion of obviousness as

"obvious to try" is incorrect. There is sufficient motivation to combine references for reasons discussed supra.

Conclusion

Claims 21-61 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 571-272-0825. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kartic Padmanabhan
Patent Examiner
Art Unit 1641

*** KP

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2/26/05